510(k) Summary

K122440

Submitter:	Coloplast A/S Holtedam 1 Humlebaek Denmark
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Date Prepared:	November 6, 2012
Device Name:	Restorelle® L
Common Name:	Surgical Mesh
Regulation:	21 CFR §878.3300
Regulatory Class:	Class II
Product Code:	OTO-Mesh, Surgical, Gynecological, For Apical Vaginal Prolapse, Transabdominally Placed.
Predicate Devices:	Restorelle® Y (K112322), Vertessa™ Polypropylene Mesh (K120327)

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Description of Device: *Restorelle* L Polypropylene Mesh is provided as a sterile mesh that is constructed of knitted non-absorbable monofilaments of polypropylene, a synthetic polymer. It consists of a flat mesh measuring 24cm x 8cm and is designed for the treatment of apical vaginal prolapse.

Indication for Use: *Restorelle* L Polypropylene Mesh is indicated for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Technological Characteristics Summary: The Coloplast *Restorelle* L shares the same materials, features, intended use, and technological characteristics as *Restorelle* Y. *Restorelle* L also shares the same materials, intended use and shape of the *Vertessa* Polypropylene Mesh. The follow table lists the properties associated with the subject and predicate devices.

Property	Subject Device Restorelle L	Predicate Device Restorelle Y	Predicate Device Vertessa Polypropylene Mesh
Indications	*Restorelle* L Polypropylene Mesh is indicated for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.	*Restorelle* Y Polypropylene Mesh is indicated for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.	Vertessa may be used for the repair of uterine or vaginal vault prolapse that requires support material. It may be used in open or laparoscopic abdominal procedures.
Materials of Construction	Non-absorbable, monofilament polypropylene mesh	Non-absorbable, monofilament polypropylene mesh	Non-absorbable, monofilament polypropylene mesh
Dimensions	24x8cm	24 x 4cm & 27 x 4cm	12x20cm / Flat
Shape	Flat	Y	Flat
Pore Size (mm)	1.80 x 1.83	1.80 x 1.83	1.47 x 0.64
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Product Code	OTO	OTO	OTO

The only difference in properties between the subject and predicate devices is size. Since the subject device falls in the range between the predicated devices, no new issues, regarding safety and efficacy, have been identified. Therefore the subject device is substantially equivalent to the cited predicate devices for indications, materials and technological features.

Performance Summary: Non-clinical performance testing, biocompatibility testing, shelf life and sterilization validations were not required for the Restorelle L since the proposed mesh is identical in materials and design as that used in the predicate Restorelle Y device. The results and data from these studies are applicable to the Restorelle L device.

Conclusions: The performance and non-clinical cited supporting this submission demonstrates that the *Restorelle* L is substantially equivalent to *Restorelle* Y and Vertessa Polypropylene Mesh.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 19, 2012

Coloplast A/S
% Mr. Tim Crabtree
Regulatory Affairs Manager
Coloplast Corp.
1601 West River Road North
MINNEAPOLIS MN 55411

Re: K122440
Trade/Device Name: Restorelle® L
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: October 10, 2012
Received: October 11, 2012

Dear Mr. Crabtree:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122440

Device Name: Restorelle® L

Indications for Use: *Restorelle* L is indicated for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122440